REMARKS

Claims 18-28, 31-35 and 39-40 are pending in this application. Claims 18-28, 31-35 and 39-40 were variously rejected under 35 U.S.C. § 103.

Applicants thank the Examiner for acknowledging withdrawal of the previous rejections under the judicially created doctrine of obviousness type double patenting.

Applicants have carefully considered the points raised in the Advisory Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejections under 35 U.S.C. §103

Claims 18-21, 24-28, and 31-35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nielsen *et al.* (WO 95/28850, "Nielsen") in view of Ghani (U.S. Pat. No. 6,120,811). Claims 22-23 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nielsen in view of Ghani and further in view of Markussen *et al.* (U.S. Pat. No. 4,106,991, "Markussen"). Claims 39-40 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Nielsen in view of Ghani and Markussen and further in view of Haarasilta (GB 2-139868A). Applicants respectfully traverse this rejection.

In support of this rejection, the Examiner asserts that the granulate taught by Nielsen contains at least 6000 FTU/g phytase and that there is no evidence that this granulate "is any different from a granulate having at least 6000 FTU/g made with an aqueous liquid comprising a phytase at a concentration of at least 14000 FTU/g liquid."[1] Previously, the Examiner has acknowledged that Nielsen does not teach a phytase-containing granulate comprising an edible carbohydrate polymer and that Nielsen does not teach a liquid phytase solution of 14,000 FTU/g of liquid.

[1] Advisory Action, page 3.

As outlined herein, Applicants respectfully submit that Nielsen does not teach a granulate that contains at least 6000 FTU/g phytase nor provides any teaching or suggestion for making a granulate with such phytase activity. Further, the secondary references do not supply what is missing from Nielsen.

Nielsen describes an animal feed additive in the form of a dry or liquid preparation. As such, the animal feed additive may be in the form of a granulated enzyme product, a stabilized liquid composition or may simply constitute the enzyme.[2] Nielsen describes that the contemplated ranges of phytase activity for the animal feed additive is from about 200 to 50,000 FYT/g, from about 500 to 10,000 FYT/g, and from about 2000 to 6000 FYT/g.[3] The Office assumes these ranges apply regardless of the form of the additive, although there is nothing in Nielsen to show this is the case. Nielsen does not indicate whether these ranges apply to a granulate, liquid or other form of animal feed additive or whether a granulate is to have all of these concentration values.

The disclosure of Nielsen fails to teach a method by which one skilled in the art can obtain a granulate having a phytase concentration of at least 6000 FTU/g because Nielsen does not teach how to obtain a liquid with sufficient phytase concentration to give this result. The only description in Nielsen of obtaining the phytase from cultured cells is on pages 6-7. Nielsen incorporates by reference EP 420358 as describing preferred techniques for producing phytase in large quantities, and states that the "phytase-containing fermentation broth is preferably treated by means of both filtration and ultra-filtration prior to being used in the formulation of the present invention."

EP 420358, of record, describes processes for producing phytase-containing solutions from culture with a range of concentrations; the highest reported concentration being 280 U/ml.[4] EP 420358 also reports that filtration and ultrafiltration of the culture medium results in

[2] Nielsen, page 10, lines 8-26.
[3] Nielsen, page 11, line 27, to page 12, line 2.
[4] EP 420358, Table 6, page 24.

approximately a 20-fold concentration of the enzyme. Thus, a phytase-containing liquid obtained from the preferred state of the art method taught in Nielsen would be expected to have a maximum phytase activity of about 5600 U/ml (280 U/ml x 20). A liquid with this concentration could not possibly be used to make a granulate having a phytase activity of 6000 FTU per gram. The granulate would have to be even more concentrated than the starting liquid, which is not possible since the liquid cannot be removed completely from the product. The following calculation is provided in support of this position.

The present specification states that the amount of phytase-containing liquid that can be added to the carrier is limited by the capacity of the carrier to absorb the liquid.[5] The lowest ratio of carbohydrate: phytase solution mentioned is about 0.5:1 (carbohydrate to enzyme liquid). Using this ratio, one can add 33 weight % of carrier and 66 weight % of phytase liquid, at the most. Such a mixture would result in an activity of the resulting granulate of 3966 U/ml (= U/g; 66% of 5600 U/ml).

The specification also teaches that up to 30% of the granulate weight can be removed by drying.[6] Accordingly, even if the granulate material lost 30% weight by drying, the maximum achievable phytase activity of the end product is 5280 U/g (3966 U/g / 70%). This best case calculation does not consider that minor amounts of salts and other material are also added, thus further decreasing the maximum activity in the final granulate.

In the working examples of Nielsen, Phytase Novo™ ranging in activity from 5000 FYT/g to 7370 FYT/g is the source of phytase enzyme. However, Nielsen does not state whether the Phytase Novo™ product is a granulate, liquid or simply purified enzyme. The Examiner has stated that "there is no teaching or suggestion in the disclosure of Nielsen et al. which would lead

[5] Specification, page 7, line 25, to page 8, line 2.
[6] Specification, page 9, lines 17-18, and page 10, lines 4-5: water content of granules before drying is between 30 and 40 weight % and after drying, water content is 3 to 10 weight %.

one of skill in the art to reasonably conclude that the phytase formulation used is in liquid or solid form."[7]

Thus, contrary to the Examiner's assertion that Nielsen describes a granulate of at least 6000 FTU/g, nothing in Nielsen teaches one of skill in the art how to produce a granulate with the claimed phytase concentration or a phytase-containing liquid as claimed.

The combination of Nielsen with the secondary reference of Ghani does nothing to cure these important defects or to supply what is missing from Nielsen. Ghani describes microgranules containing an enzyme, a carrier such as soy flour, soy grits, corn flour, etc., and other components. Ghani does not teach or suggest a granulate with at least 6000 FTU/g phytase nor such a granulate formed by the use of an aqueous liquid comprising a phytase at a concentration of at least 14,000 FTU/g of aqueous liquid. Ghani provides no information on how to obtain a granulate with at least 6000 FTU/g phytase or an aqueous liquid preparation with a phytase activity of at least 14,000 FTU/g of liquid.

Thus, neither Nielsen or Ghani, alone or in combination, teaches or suggests all the limitations of the claimed invention. Nothing in Nielsen and Ghani provides a disclosure which would enable a skilled artisan to produce a granulate having a phytase activity of at least 6000 FTU/g. Given the silence in the cited references on required elements of the claims, the cited references do not render the claims obvious.

The secondary reference Markussen describes derivatized cellulose in enzyme granulates but does not describe phytase-containing granulates. Markussen does not supply what is missing from Nielsen or from the combination of Nielsen and Ghani. The combination of Nielsen, Ghani and Markussen does not teach or suggest the claimed invention and does not provide a disclosure which would enable a skilled artisan to produce a granulate having a phytase activity as claimed. Thus, Markussen, Nielsen and Ghani do not render the claimed invention obvious.

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[7] Final Office Action, mailed November 3, 2003, page 6.

The secondary reference Haarasilta describes granulated cattle fodder with soya bean oil but does not describe phytase-containing granulates. Haarasilta does not supply what is missing from Nielsen or from the combination of Nielsen, Ghani and Markussen. The combination of Nielsen, Ghani, Markussen and Haarasilta does not teach or suggest the claimed invention, thus does not render the claimed invention obvious.

In sum, none of the references, either alone or in combination, describes or suggests a granulate having a phytase activity of at least 6000 FTU per gram of granulate or the use of a phytase-containing aqueous liquid of at least 14,000 FTU phytase per gram of liquid in the preparation of such a granulate. As outlined herein, the references do not provide a disclosure which would enable a skilled artisan to produce a granulate having a phytase activity of at least 6000 FTU per gram. Thus, the cited references do not teach or suggest required elements of the claims.

Accordingly, the cited references do not support *prima facie* obviousness with regard to the claimed invention.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

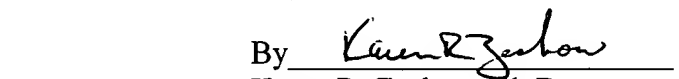
CONCLUSION

Applicants believe that all issues raised in the outstanding Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 251502008600. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 3, 2004

Respectfully submitted,

By 

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